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Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

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NORME EUROPÉENNE
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EN 61675-1

June 2014

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Supersedes EN 61675-1:1998

English Version

**Radionuclide imaging devices - Characteristics and test
conditions - Part 1: Positron emission tomographs
(IEC 61675-1:2013)**

Dispositifs d'imagerie par radionucléides - Caractéristiques
et conditions d'essai - Partie 1: Tomographes à émission de
positrons
(CEI 61675-1:2013)

Bildgebende Systeme in der Nuklearmedizin - Merkmale
und Prüfbedingungen - Teil 1: Positronen-Emissions-
Tomographen
(IEC 61675-1:2013)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

The text of document 62C/550/CDV, future edition 2 of IEC 61675-1, prepared by IEC/SC 62C, "Equipment for radiotherapy, nuclear medicine and radiation dosimetry", of IEC TC 62, "Electrical equipment in medical practice " was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 61675-1:2014.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2014-12-13
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Annex ZA

(normative)

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NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-



IEC 61675-1

Edition 2.0 2013-09

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Radionuclide imaging devices – Characteristics and test conditions –
Part 1: Positron emission tomographs**

**Dispositifs d'imagerie par radionucléides – Caractéristiques et conditions
d'essai –
Partie 1: Tomographes à émission de positrons**



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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
1 Scope.....	7
2 Normative references	7
3 Terms and definitions	7
4 Test methods.....	13
4.1 General.....	13
4.2 SPATIAL RESOLUTION	13
4.2.1 General	13
4.2.3 Method	14
4.2.4 Analysis.....	15
4.2.5 Report	17
4.3 Tomographic sensitivity.....	18
4.3.1 General	18
4.3.2 Purpose.....	18
4.3.3 Method	18
4.3.4 Analysis.....	19
4.3.5 Report	20
4.4 Uniformity	20
4.5 Scatter measurement.....	20
4.5.1 General	20
4.5.2 Purpose.....	20
4.5.3 Method	20
4.5.4 Analysis.....	21
4.5.5 Report	22
4.6 PET COUNT RATE PERFORMANCE	23
4.6.1 General	23
4.6.2 Purpose.....	23
4.6.3 Method	23
4.6.4 Analysis.....	24
4.6.5 Report	26
4.7 Image quality and quantification accuracy of source ACTIVITY concentrations	26
4.7.1 General	26
4.7.2 Purpose.....	26
4.7.3 Method	27
4.7.4 Data analysis.....	31
4.7.5 Report	34
5 ACCOMPANYING DOCUMENTS	35
5.1 General.....	35
5.2 Design parameters.....	35
5.3 Configuration of the tomograph	36
5.4 SPATIAL RESOLUTION	36
5.5 Sensitivity	36
5.6 SCATTER FRACTION.....	36
5.7 COUNT RATE performance	36

5.8	Image quality and quantification accuracy of source ACTIVITY concentrations	36
	Bibliography.....	37
	Index of defined terms	38
	Figure 1 – Evaluation of FWHM	16
	Figure 2 – Evaluation of EQUIVALENT WIDTH (<i>EW</i>).....	17
	Figure 3 – Scatter phantom configuration and position on the imaging bed	19
	Figure 4 – Evaluation of SCATTER FRACTION	22
	Figure 5 – Cross-section of body phantom	27
	Figure 6 – Phantom insert with hollow spheres	28
	Figure 7 – Image quality phantom and scatter phantom position for whole body scan acquisition	29
	Figure 8 – Placement of ROIs in the phantom background	32

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**RADIONUCLIDE IMAGING DEVICES –
CHARACTERISTICS AND TEST CONDITIONS –****Part 1: Positron emission tomographs**

FOREWORD

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International Standard IEC 61675-1 has been prepared by subcommittee 62C: Equipment for radiotherapy, nuclear medicine and radiation dosimetry, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition replaces the first edition of IEC 61675-1, published in 1998. This edition constitutes a technical revision. Requirements have been changed regarding the following technical aspects:

- SPATIAL RESOLUTION;
- sensitivity measurement;
- SCATTER FRACTION;
- COUNT RATE performance;
- image quality.

The text of this standard is based on the following documents:

CDV	Report on voting
62C/550/CDV	62C/561/RVC

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

References to clauses within this standard are preceded by the term “clause” followed by the clause number. References to subclauses within this particular standard are by number only.

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The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

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INTRODUCTION

Further developments of POSITRON EMISSION TOMOGRAPHS allow most of the tomographs to be operated in fully 3D acquisition mode. To comply with this trend, this standard describes test conditions in accordance with this acquisition characteristic. In addition, today a POSITRON EMISSION TOMOGRAPH often includes X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT). For this standard PET-CT hybrid devices are considered to be state of the art, dedicated POSITRON EMISSION TOMOGRAPHS not including the X-ray component being special cases only.

The test methods specified in this part of IEC 61675 have been selected to reflect as much as possible the clinical use of POSITRON EMISSION TOMOGRAPHS. It is intended that the tests be carried out by MANUFACTURERS, thereby enabling them to declare the characteristics of POSITRON EMISSION TOMOGRAPHS in the ACCOMPANYING DOCUMENTS. This standard does not indicate which tests will be performed by the MANUFACTURER on an individual tomograph.

RADIONUCLIDE IMAGING DEVICES – CHARACTERISTICS AND TEST CONDITIONS –

Part 1: Positron emission tomographs

1 Scope

This part of IEC 61675 specifies terminology and test methods for declaring the characteristics of POSITRON EMISSION TOMOGRAPHS. POSITRON EMISSION TOMOGRAPHS detect the ANNIHILATION RADIATION of positron emitting RADIONUCLIDES by COINCIDENCE DETECTION.

No test has been specified to characterize the uniformity of reconstructed images, because all methods known so far will mostly reflect the noise in the image.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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